DEC 19 2013

1.0 Submitter Information

1.1 This Premarket Notification is submitted by:

Delphinus Medical Technologies, Inc.
46701 commerce Center Drive
Plymouth, Michigan 48170

1.2 Contact Information:

Contact Name: Andrea N. Wallen
Telephone: 734-306-1069
Fax: 734-207-3165
E-mail: awallen@delphinusmt.com

1.3 Date: October 2, 2012

2.0 Device Name

2.1 Trade/ Proprietary Name: SoftVue

2.2 Common Name:

- System, Imaging, Pulsed Echo Ultrasonic
- Transducer, Ultrasonic, Diagnostic

2.3 Classification Name:

- 21 CFR § 892.1560: Ultrasonic pulsed echo imaging system
- 21 CFR § 892-1570: Diagnostic ultrasonic transducer

3.0 Predicate Device

The predicate device is identified as the Sofia™ (ATUS) Imaging Device manufactured (ATUS) by iVu Imaging Corporation. The Sofia™ (ATUS) Imaging Device received market clearance under 510(k) number K080555.

4.0 Device Description

SoftVue is an automated tomographic B-mode diagnostic ultrasound system to be used as an adjunct to mammography for imaging a patient's breast. SoftVue is comprised of the following subsystems: the Transducer, Table/Housing, Water Control System, Computer Control System, Image Reconstruction System, Power System, and the Data Acquisition System.

SoftVue has a built-in curvilinear transducer that is used to acquire ultrasound images. Images are acquired from a patient lying prone on the table with their breast submerged in an imaging chamber filled with warm (body temperature) water. The breast is positioned in the center of the transducer. A camera, located at the bottom of the imaging chamber provides a live video feed to the system operator to aid in positioning the patient's breast. Once the scan is initiated, the transducer collects data that are processed to produce a series of ultrasound image slices that can be stacked to yield a volumetric ultrasound image of the breast.

The Water Control System is used to de-gas and warm the water that is used as the image acquisition medium. The Computer Control System controls all of the functionality of the other subsystems. The reconstruction engine processes the image data acquired by the transducer ring into B-mode ultrasound images.

The system includes a barcode reader, touchscreen console (user interface), and display monitor. The touchscreen console and monitor allow the clinical user to perform an imaging procedure on a patient. Patient information is entered into the system using either the touchscreen console or the barcode reader. Device errors and warnings are displayed on the console and/or display.

SoftVue outputs the images to an Image Storage Medium that allows the images to be stored until they are reviewed on a workstation or transferred via DICOM to a PACS environment.

5.0 Intended Use

SoftVue™ is indicated for use as a B-mode ultrasonic imaging system for imaging of a patient's breast when used with an automatic scanning curvilinear array transducer. The device is not intended to be used as a replacement for screening mammography.

6.0 Predicate Device Comparison

Delphinus Medical Technologies claims that the SoftVue device is substantially equivalent to the Sofia (ATUS) Imaging Device cleared by the FDA in K080555. Delphinus Medical Technologies claims substantial equivalence because the proposed device has an equivalent intended use, manufacturing materials, operating principles, physical and operational specifications as compared to the predicate device.

The SoftVue device and the predicate device utilize B-mode grayscale ultrasound images to achieve their intended use. Both the Sofia (ATUS) and SoftVue are table-top systems and have automatic scanning transducers to image breast tissue.

The specific details regarding similarities and differences between SoftVue and iVu Sofia have been identified and explained in the Comparison Table section provided in Section 10 of this submission. A brief summary of the similarities and differences between SoftVue™ and the Sofia (ATUS) Imaging Device is included below. The differences noted between SoftVue™ and the Sofia (ATUS) do not present any new issues related to safety and effectiveness.

Similarities:

- Similar to the Sofia™ (ATUS), SoftVue uses an automated transducer to acquire 2D images of a patient's breast.
- SoftVue™ and the Sofia™ (ATUS) use broadband transducers.
- Both systems acquire and process B-mode grayscale images of a patient's breast.
- SoftVue™ and the Sofia™ (ATUS) position the patient in a prone position lying on their examination table with the patient's in a pendulous position within an imaging chamber.
- Both the SoftVue™ and Sofia™ (ATUS) position the patient's breast in a fluid environment to eliminate the need for breast compression and facilitate the transmission of ultrasound waves.

Differences:

- The Sofia™ (ATUS) utilizes a commercially available 510(k) approved linear transducer manufactured by GE Medical Systems. SoftVue™ uses a custom curvilinear transducer manufactured for Delphinus Medical Technologies.
- The Sofia™ (ATUS) utilizes a frequency range of 5-13 MHz, whereas SoftVue™ has a single operating frequency of 3 MHz.

7.0 Summary of Testing

The function and performance of SoftVue™ will be evaluated through non-clinical design verification and validation testing. Testing includes system performance and simulated use tests. The results of the evaluation tests will demonstrate that SoftVue™ successfully meets the requirements of its intended use.

Delphinus Medical Technologies conducted performance evaluations to verify that SoftVue's subsystems successfully meet predetermined specifications and product performance requirements. Results of the testing performed demonstrate that SoftVue's subsystems meet the system and performance requirements necessary for its intended use. A brief list of some of the testing performed is included below.

- Acoustic output testing – Meets the Global Maximum Output
- Sub-system Verification Testing – All requirements were met.

System Verification and Validation Testing will be performed using an anthropomorphic phantom breast designed for measuring resolution and contrast. The breast phantom was seeded with 18 inclusions located in specific locations within the phantom.

In addition to the tests listed above, SoftVue™ will also undergo testing to the safety standards listed in Table 3-1 prior to market release.

Table 3 - 1: Safety Testing to be Performed on SoftVue

Standard # and Date	Standard Title
IEC 60601-1:2005	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
IEC 60601-1-1:2000	Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems.
IEC 60601-1-2:2007	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004)
IEC 60601-1-4:2000	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems, edition 1.1
IEC 60601-2-37:2007	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

8.0 Conclusion

SoftVue performs as intended and is substantially equivalent to the Sofia (ATUS) Imaging Device with respect to intended use, design, principles of operation, technology, materials, and performance. Any noted differences do not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2013

Delphinus Medical Technologies, Inc.
% Ms Andrea Wallen
Director of Quality and Regulatory Affairs
46701 Commerce Center Drive
PLYMOUTH MI 48170

Re: K123209
Trade/Device Name: SoftVue
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: November 27, 2013
Received: December 02, 2013

Dear Ms. Wallen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

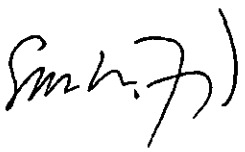
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K123209

Device Name

SoftVue

Indications for Use *(Describe)*

SoftVue™ is indicated for use as a B-mode ultrasonic imaging system for imaging of a patient's breast when used with an automatic scanning curvilinear array transducer. The device is not intended to be used as a replacement for screening mammography.

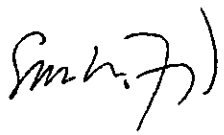
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use

System: SoftVue

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Breast)	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comments: SoftVue is intended for ultrasonic breast examinations

Concurrence of Center for Devices and Radiological Health (CDRH)